UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RAINER OSCHMANN and ECKHARDT GRETHLEIN

Appeal 2007-0183
Application 09/720,940
Technology Center 1600

ON BRIEF

Before MILLS, GRIMES, and LEBOVITZ, *Administrative Patent Judges.*

MILLS, *Administrative Patent Judge.*

DECISION ON APPEAL

Appellants appeal the Examiner's final rejection of claims 11-18 for obviousness-type double patenting over five different patents, and under 35 U.S.C. § 103 for obviousness. The Examiner's answer withdraws a 35 U.S.C. § 102(b) rejection. We have jurisdiction under 35 U.S.C. § 6(b) (2002).

We affirm.

BACKGROUND

Pharmaceutical and cosmetic utilities exist for preparations based on Ginkgo biloba leaf extracts. Specification, p.1, ll. 14-18. According to the specification, extracts of Gingko biloba can be characterized by water solubility, concentration, and by mass of known, active chemical constituents, such as ginkgolides and bilobalide. Specification, p.2, ll. 18-25. Some prior art Gingko biloba extracts contain solubilization agents or other galenic aids. Specification p.4, ll. 3-8.

The specification, page 9, states that the advantageous water solubility of the claimed extract is accomplished by ultrafiltration. Specification, p.9, ll. 1-9. An example of the composition of an extract obtained by the ultrafiltration method is found in Example 3 on pages 14-15 of the specification and includes terpenlactone - 6.77%, ginkgolides A, B, and C - 3.49%, bilobalide - 3.28%, flavonglycosides – 26.02% and gingkolic acids <5%.

DISCUSSION

1. Claim Interpretation

Claim 11 is directed to:

> A water-soluble, native dry extract consisting essentially of Ginkgo biloba plant part constituents, wherein the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons and wherein the extract lacks any solubilization agents.

It is well settled that during ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). With this in mind, we interpret Claim 11 before us.

Claim 11 is a product-by-process claim. "Even though product-by-process claims are limited, and defined, by the process, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, the product of Claim 11 is a water soluble extract of Ginkgo biloba. The extract is a dry extract. Claim 11 further recites that the dry extract "consists essentially of" Ginkgo biloba plant part constituents. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps" and those that do not *materially* affect the

basic and *novel* characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

The specification, page 9, states that ultrafiltration results in advantageous water solubility of the claimed extract. Specification, p.9, ll. 1-9. An example of the composition of an extract obtained by the ultrafiltration method is found in Example 3 on pages 14-15 of the specification and includes terpenlactone - 6.77%, ginkgolides A, B, and C - 3.49%, bilobalide - 3.28%, flavonglycosides – 26.02% and gingkolic acids <5%.

Appellants do not specifically define in the specification what types of plant constituents are excluded or included by the claim language "consisting essentially of" in the claim. Appellants do not define any additional basic and novel characteristics or properties of the Gingko biloba extract, other than that it is water soluble. Thus, we construe the claim language "consisting essentially of," in Claim 11, as limited to an extract which has the basic characteristic of being water soluble; the extract is also dry.

Again, claim 11 recites that the "extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons" and the extract lacks any solubilization agents. The

specification does not specifically indicate which of the prior art extract constituents are excluded by filtration having an average molecular weight cut off ranging from 2000 to 10000 Daltons.

According to Appellants, all claims on appeal stand or fall together for each rejection before us. Brief, pages 2-3. We select claim 11 as representative of the subject matter on appeal. 37 CFR § 41.37(c)(1)(vii).

2. Obviousness-Type Double Patenting

To determine if obviousness-type double patenting is present, one must determine if any claim in the application at issue defines merely an obvious variation of an invention disclosed and claimed in the cited patents. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 621-22 (CCPA 1970). The disclosure of a reference patent *may not be used as prior art*; in certain situations, however, it may be used to define terms in claims and to determine whether an embodiment claimed was modified in an obvious manner. *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 940, 220 USPQ 481, 487 (Fed. Cir. 1983).

"Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an

unobvious difference between the claimed product and the prior art product." *In re Marosi*, 710 F.2d 799, 803, 218 USPQ 289, 292-93 (Fed. Cir. 1983).

We sustain the Examiner's rejections for obviousness-type double patenting. Our reasoning for this determination follows.

A. *U.S. Patent No. 6,328,999 ('999)*[1]

Claims 11-18 stand rejected for obviousness-type double patenting over claim 1 of U.S. Patent No. 6,328,999.

Claim 1 of the '999 patent is directed to an:

> 1. Extract from ginkgo biloba leaves comprising:
> 20 to 30% by weight flavonol glycosides;
> a total of 2.5 to 4.5% by weight of ginkgolides A, B, C and J;
> 2.0 to 4.0% by weight bilobalide;
> below 10 ppm alkyl phenol compounds;
> below 10% by weight proanthocyanidins;
> below 50 ppm 4'-O-methyl pyridoxine;
> below 100 ppm biflavones.

Turning to the '999 disclosure to define the term extract, as permitted under *Wahl*, 724 F.2d at 940, the '999 specification teaches that the Ginkgo biloba extract is dry. '999, col. 3, l. 6; col. 4, ll. 9, 22-33.

Pointing to claim 1 of the '999 Patent, the Examiner contends that although the instant claims differ from the claim by the recitation that the

[1] Issued December, 2001.

extract "is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons[,] the ultrafiltration process limitation in the claim fails to render the instant invention nonobvious. Answer, page 4. The Examiner argues that, "even though product-by-process claims are limited and defined by the process, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985).

Appellants contend that:

> the present inventive extract necessar[ily] consists essentially of constituents having an average molecular cut off weight of less than 10000 Daltons, as the extract is formed by the claimed ultrafiltration. As stated in the specification at page 9, line 1 et seq., this ultrafiltration *removes or deactivates* components which "impede the water solubility of dry extracts" and results in a novel extract with excellent water solubility properties. In other words, as clear from the specification, the resultant product created by the ultrafiltration is different and novel over non-ultrafiltered Gingko leaf extracts, which contain particles much larger than 10000 Daltons, and do not consist essentially of the ultrafiltered particles as recited in claim 1. Brief, page 3 (emphasis added).

Focusing, therefore, on the product, the Examiner provides evidence that the active compounds in the Ginkgo biloba extract of '999 Claim 1 have molecular weights of less than 2,000 Daltons. Answer, page 4. In particular, evidence is provided that the extract of '999, claim 1 contains similar amounts of flavonol glycosides, ginkgosides, and bilobalides as

Example 3 of the specification which has undergone the process of ultrafiltration in Appellants' Claim 11, and, therefore, is an embodiment of '999 Claim 1. Thus, we agree that the extract of the '999 patent would reasonably appear to meet the claim requirement that the extract have a molecular cut off of 2000 to 10000 Daltons, and thus is encompassed by pending claim 1.

Appellants attribute the solubility properties of the claimed extract to the requirement that the extract constituents have a molecular weight less than 10000 Daltons. Thus, it follows that if the components of the prior art gingko biloba extract have a molecular weight less than 10000 Daltons, it is reasonable to presume that the prior art extracts have water solubility similar to that of the claimed extract. Therefore, in our view the Examiner has provided sufficient evidence to establish a prima facie case of obviousness-type double patenting.

Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Appellants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Although Appellants present attorney argument that the '999 extract contains particles much larger than 10000 Daltons, Appellants present no evidence to support this position. Appellants point to no evidence in the record or otherwise which would suggest that the '999 extract contains compounds much greater than 10000 Daltons.

Appellants are reminded that arguments of counsel cannot take the place of evidence. *In re DeBlauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984), *In re Payne*, 606 F.2d 303, 315, 203 USPQ 245, 256 (CCPA 1979); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Appellants do not present any showing of data to the effect that "the claimed extract has properties not possessed by the prior art compositions or that they possessed them to an unexpectedly greater degree." *In re Dillon*, 919 F.2d 688, 693 (Fed. Cir. 1990). As we are presented with no objective evidence or arguments supporting Appellants' assertions, the obviousness-type double patenting rejection with respect to the '999 Patent stands affirmed.

B. U.S. Patent No. 5,512,286 ('286)[2]

Claims 11-18 stand rejected for obviousness-type double patenting over claims 1-14 of U.S. Patent No. 5,512,286.

The '286 patent teaches a dry extract of Gingko biloba, *see col.3, l.28, col.6, l.64, col.7, l.62, col.8, l.49, col.10, l.45.* Claim 1 of the '286 Patent reads as follows:

> 1. An extract from the leaves of Ginkgo biloba containing most of the flavone glycosides, ginkgolides and bilobalide originally present in the leaves, comprising 20 to 30 weight percent flavone glycosides, 2.5 to 4.5 weight percent ginkgolides selected from the group consisting of ginkgolide A, B, C and J and mixtures thereof, 2.0 to 4.0 weight percent bilobalide and less than 10 ppm alkylphenol compounds, said extract being essentially free of components of the leaves with serum-precipitating or hemagglutinating properties.

The Examiner contends that, Appellants' "process of ultrafiltration and cut off range of 2,000 to 10,000 Daltons will produce a product that is obvious over the prior art." Answer, page 5.

Appellants assert that the '286 Patent does not teach that the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons, rendering the claimed product different from that claimed in the '286 patent. Brief, page 4. However, Appellants present no evidence showing that the claimed extract differs from the extract disclosed in the '286 patent. Nor do Appellants represent that

[2] Issued April, 1996.

any other specific compound present in the prior art Gingko biloba extracts would materially alter the "basic and novel" solubility characteristics of the claimed Gingko biloba extract. Accordingly, the rejection of the claims for obviousness-type double patenting in view of the '286 patent is affirmed.

C. U.S. Patent No. 6,399,099 ('099)[3]

Claims 11-18 stand rejected for obviousness-type double patenting over claims 1-25 of U.S. Patent No. 6,399,099.

The '099 Patent claims:

> 1. An effervescent composition for oral administration comprising
>
> (a) a dry extract of ginkgo biloba comprising from 20-30% by weight of flavone glycosides and from about 4.5-8.5% by weight of terpenoids;[4]
>
> (b) an effervescent mixture of a physiologically acceptable acid or sodium salt thereof; and
>
> (c) a physiologically acceptable carbonate or hydrogen carbonate in a weight ratio of (b) to (c) of about 1:1 to 1:3,
>
> where the resulting solution after adding water has a pH value of 6 to 8 and is stable for at least one hour.

Thus, the '099 patent claims a dry extract composition.

Appellants assert that the '099 patent does not teach that "the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons" rendering the claimed

[3] Issued June, 2002.
[4] Note that the specification, page 6, indicates that an extract produced by the claimed process includes 5-7% terpenlactones.

product different from that claimed in the '099 patent. Brief, page 4. However, Appellants present no evidence showing a difference between the claimed extract and that claimed in the '099 Patent.

We affirm the obviousness-type double patenting rejection over claims 1-25 of the '099 Patent.

D. U.S. Patent No. 5,399,348 ('348)[5]

Claims 11-18 stand rejected for obviousness-type double patenting over claims 1-25 of U.S. Patent No. 5,399,348.

The '348 Patent claims:

> 1. An extract comprising 20 to 30 weight percent flavone glycosides, 2.5 to 4.5 weight percent of ginkogolides A, B, C and J, 2.0 to 4.0 weight percent bilobalide, less than 10 ppm alkylphenol compounds and less than 10 weight percent proanthocyanidins.

The extract can be dry. '348, col. 7, l. 22, col. 8, l. 26.

Appellants assert that the '348 patent does not teach that "the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons" rendering the claimed product different from that claimed in the '348 patent. Brief, pages 4-5.

We do not agree that the extract claimed in the '348 patent, Claim 1, contains similar amounts of flavonol glycosides, ginkgosides, and

5 Issued March, 1995.

bilobalides as Example 3 of the instant specification, which has undergone the process of ultrafiltration. Specification, pages 14-15. Appellants present no evidence showing a difference in solubility between the claimed extract and that claimed in the '348 Patent. Therefore, Appellants have failed to rebut the Examiner's prima facie case of obviousness-type double patenting.

We sustain the obviousness-type double patenting rejection over claims of the '348 Patent.

E. *U.S. Patent No. 5,322,688 ('688)*[6]

Claims 11-18 stand rejected over claim 12 of U.S. Patent No. 5,322,688.

Claim 12 of the '688 patent is directed to "an extract from the leaves of *Ginkgo biloba*, which is substantially free of alkylphenol compounds, and having a high content of flavone glycosides and comprising substantially all of the ginkgolides and bilobalide originally present in the leaves." Answer, page 8.

Appellants assert that the '688 patent does not teach that "the extract is produced by ultrafiltration using a filter having an average molecular weight cut off ranging from 2000 to 10000 Daltons" rendering the claimed

6 Issued June, 1994.

product different from that claimed in the '688 Patent. Brief, page 5. However, the extract taught in the '688 patent contains similar amounts of flavonol glycosides, ginkgosides, and bilobalides as Example 3 of the instant specification. '688, col.4, ll. 50-55, col. 5, ll. 7-11; Specification, pages 14-15. Appellants present no evidence to rebut the Examiner's *prima facie* case of obviousness-type double patenting. No other evidence before us shows that the claimed extract differs in solubility from that of Claim 12 of the '688 Patent.

Accordingly, we sustain the obviousness-type double patenting rejection with respect to the '688 Patent.

3. 35 U.S.C. § 103

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *See In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). With this as background, we

analyze the prior art applied by the Examiner in the rejection of the claims on appeal.

A. Japanese unexamined patent publication 279,300 ('300)[7]

Claims 11-18 stand rejected under 35 U.S.C. §103 for obviousness over the '300 publication.

Appellants and Examiner agree that the '300 publication fails to teach a Gingko biloba extract obtained by ultrafiltration. Final Rejection, page 12; Brief, page 6.

Appellants argue that the '300 publication makes no "indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious." Brief, page 6. This argument of Appellants is not persuasive. The appropriate analysis of obviousness of a product by process claimed is not whether the use of ultrafiltration process would have been obvious, but whether the product of the '300 publication's Gingko biloba extract and the product of the claimed process possess distinct properties.

If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the

7 Published April, 1994. [Translation provided]

prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).

We agree with the Examiner that the '300 publication teaches a water-soluble extract having compounds less than 2,000 Daltons. Appellants have presented no evidence to show a difference between the two facially equivalent extracts. Answer, page 11. The rejection of the claims for obviousness over the '300 publication is sustained.

B. The Liu Study

Claims 1-18 stand rejected under 35 U.S.C. § 103 for obviousness over Liu.[8]

The Examiner argues that by claiming an extract obtained by "ultrafiltration cut off range 2,000 to 10,000 Daltons," the "[i]nstant claims differ from the reference." Answer, page 10. Although Liu does not teach ultrafiltration with molecular weight cutoffs of 2,000 to 10,000 Daltons, "it teaches the water-soluble extract, which contains compounds of less than 2,000 Daltons." Answer, page 10. The Examiner argues that

> [t]he resultant product is *not* different because after the ultrafiltration . . . the filtrate contains the compounds having molecular weight of less than 2,000 Daltons [which] include many

[8] Liu Zheng et al. (Liu) AN 1997:82596, HCAPLUS, abstract of Huaxue Shijie, Vol. 37, No. 7, pp. 355-358 (1996) [English translation provided.]

> active compounds present in *Ginkgo biloba* extract (already on the market), such as flavones, flavonglycosides, terpenlactones, and bilobalide. Answer, page 11.

Thus, we agree that the Examiner has presented sufficient evidence to establish a prima facie case of obviousness over Liu.

Appellants argue that the reference makes no "indication or assertion that an extract produced by ultrafiltration using such a filter size would have been obvious." Brief, page 6. On the contrary, the Examiner spells out the lack of distinction between the claimed extract and the extract disclosed in Liu. In light of these considerations, we do not find that Appellants have presented sufficient argument or evidence to rebut the Examiner's prima facie case of obviousness. We sustain the 35 U.S.C. § 103 obviousness rejection of claims 1-18 over Liu.

CONCLUSION

The rejections of claims 11-18 for obviousness-type double patenting over the '999 patent, the '286 patent, the '099 patent, the '348 patent, and the '688 patent are sustained. The 35 U.S.C. § 103 rejections of claims 11-18 for obviousness over Japanese unexamined patent publication 279,300 and Liu, are also sustained.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Demetra J. Mills)
Administrative Patent Judge)
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